UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FWK HOLDINGS, LLC, on behalf of itself and all others similarly situated,

Plaintiff,

v.

SANOFI, U.S. and SANOFI GmbH,

Defendants.

Civil Action No. _____

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. The plaintiff, FWK Holdings, LLC, on behalf of itself and all others similarly situated, for its complaint against the defendants, Sanofi, U.S. and Sanofi GmbH, allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

2. This is a civil antitrust action challenging the defendants' unlawful impairment of competition in the market for insulin glargine for injection. Sanofi used a variety of anticompetitive practices as part of an overall scheme to block follow-on competition for its branded insulin glargine products, Lantus and Lantus SoloSTAR. The plaintiff and the class of direct purchasers on whose behalf this action is brought were harmed by Sanofi's unlawful monopolistic acts.

3. Sixteen years ago, on April 20, 2000, the U.S. Food and Drug Administration ("FDA") approved insulin glargine as a long-acting analog insulin for management of diabetes. By May 2001, Sanofi was commercially selling vials and injector cartridge formulations of the drug in the U.S. under the trademark Lantus (and later as Lantus SoloSTAR, another injector pen formulation). In August 2014, the Sanofi patent that claimed insulin glargine and disclosed the components of its formulation expired; six months later, on February 12, 2015, the "pediatric exclusivity" attached to that patent also expired. That ended Sanofi's lawful exclusivity for insulin glargine. By then, Sanofi had enjoyed many billions of dollars in sales based on that compound. At that point, the invention of insulin glargine passed into the public domain, and follow-on competition should have been permitted to enter the U.S. market, just as it had elsewhere around the world.

4. Eli Lilly and Company, a leader in pharmaceutical products and a long-time supplier of insulins to diabetic patients worldwide, sought to do just that. For years – and

working with its development partner Boehringer Ingelheim – Lilly developed a follow-on insulin glargine product for worldwide distribution. In 2013, it filed with the FDA a New Drug Application for approval to sell insulin glargine in the U.S. beginning in February 2015, i.e., upon expiration of the U.S. insulin glargine patent and its pediatric exclusivity.

5. But Sanofi had erected a regulatory roadblock by unlawfully listing *other* patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") that either did not belong there, or did not even cover all Lantus formulations; the false filings required Lilly to inform Sanofi of Lilly's efforts to gain FDA approval. Lilly provided Sanofi with confidential documents identifying the active and inactive ingredients of Lilly's insulin glargine product and an injector pen by which it may be administered. The documents showed the Lilly insulin glargine injector product did not infringe any of the other Sanofi patents.

6. Sanofi sued Lilly anyway on two patents disclosing examples of insulin glargine formulations in which a different ingredient, polysorbate 20 or 80, was added. (Sanofi had begun adding polysorbate 20 to *vials* of Lantus in around 2005, though the Lantus in its injector pens remained unchanged). Sanofi also asserted two patents issuing from an application filed over 10 years prior by a British design company directed to an injector pen different from Lilly's.

7. Sanofi's suit lacked any reasonable basis. But merely by bringing the claims, Sanofi caused a 30-month delay of FDA approval of Lilly's NDA for insulin glargine. This 30-month delay of FDA approval, extending beyond the February 2015 expiration of exclusivity from the Sanofi insulin glargine patent, prevented Lilly from marketing its own insulin glargine drug product.

8. Eventually, Sanofi and Lilly settled the suit over the U.S. patents, but by then Sanofi's scheme to delay Lilly's efforts to gain U.S. market entry had worked. Sanofi granted Lilly a *global* license to sell the Lilly injector insulin glargine product worldwide, but competition from Lilly's product would not begin in the U.S. until December 2016, almost two years after the technology for insulin glargine had become publicly available for use by Lilly and others in this country.

9. Were it not for Sanofi's unlawful Orange Book listings and its baseless suit against Lilly, follow-on competition from insulin glargine products would have commenced on or soon after the mid-February 2015 expiry of the lawful monopoly over insulin glargine. For a market where the gross revenues topped well over $7 billion in 2014 alone, the savings to American purchasers of insulin glargine would have far exceeded a billion dollars.

10. This suit, brought under federal antitrust laws, seeks to recover the overcharges sustained by direct purchasers of Lantus and Lantus SoloSTAR as a result of the defendants' unlawful and anticompetitive practices.

II. PARTIES

11. The plaintiff, FWK Holdings, LLC ("FWK" or "plaintiff"), is a corporation organized under the laws of the State of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Co., which, during the class period, as defined below, purchased Lantus and Lantus SoloSTAR, and would have purchased Lilly's competing insulin glargine product, had it been available.

12. The defendant Sanofi U.S. is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

13. The defendant Sanofi GmbH is a German corporation, with its principal place of business located at Industriepark Hoechst, Bldg. K607, Frankfurt Am Main, Germany D-65926.

14. Sanofi U.S. and Sanofi GmbH shall be referenced collectively in this complaint as "Sanofi."

III. JURISDICTION AND VENUE

15. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiff and members of the class resulting from Sanofi's unlawful monopolization of the United States market for insulin glargine. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331(a) and (d), 1337(a), and 15 U.S.C. § 15.

16. Venue is appropriate within this district under 15 U.S.C. §§ 15(a), 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b), (c), and (d) (general venue provisions).

17. Sanofi transacts business within this district, transacts its affairs and carries out interstate trade and commerce in substantial part in this district, and/or it or its agents may be found in this district.

18. Sanofi's conduct was within the flow of, was intended to, and did have a substantial effect on interstate commerce of the United States, including in this district.

19. During the class period, Sanofi manufactured, sold, and shipped Lantus and Lantus SoloSTAR in an uninterrupted flow of interstate commerce.

20. During the class period, Sanofi or one or more of its affiliates used the instrumentalities of interstate commerce to join or effectuate the conspiracy. The scheme in

which Sanofi participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

21. This Court has personal jurisdiction over Sanofi. Sanofi has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States and including in this district. The scheme was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. INDUSTRY BACKGROUND

22. Branded drug companies can obtain valid patents that cover their new prescription drug products. Such patents encourage discovery and development of new medicines, providing protection from competition by other drug companies for a length of time set under a statute by Congress.

23. Once the lawful periods of exclusivity expire on brand products – once the disclosures in the brand company's patent enter the public domain – companies seeking to market generic drugs, follow-on biologics, or biosimilar products can seek FDA approval to sell competing identical or similar versions of the brand, allowing those companies to manufacture products that are just as safe and effective as, but less expensive than, the brand. The medication becomes more affordable for purchasers, who are no longer burdened by the high cost of the brand drug.

24. Brand companies are required to provide to the FDA information about patents claiming their particular drug product. The FDA must rely, completely, on the information provided by the brand and list those patents publicly, so that competitors understand the scope of the brand's ostensible patent protection. Would-be competitors must wait until the expiration of all listed patents, unless they can certify that their product does not infringe one

or more listed patents. Such a certification may trigger the brand company to sue for patent infringement – but a brand company may do so only if it has an objectively reasonable basis to claim the patent's protection. The listed patents, would-be competitors' certifications, and brand company's suits all affect the timing of FDA approval for less expensive products.

25. So branded drug companies have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture. But it is a limited period, after which would-be competitors may enter the market with lower-cost substitutes. And the timing of approval of these competing products depends on, among other things, the truthfulness of the patent information provided by the brand to the FDA.

26. From this industry framework, two rules emerge. First, brand drug companies cannot provide false or misleading patent information to the FDA and wield that information to delay entry of medications containing the same molecule as the brand product beyond the expiration of legitimate patent protection. Second, drug companies cannot file patent infringement lawsuits against would-be competitors when the action has no realistic likelihood of success of the merits; the mere filing of such a lawsuit stalls legitimate efforts to gain market entry.

27. Sanofi broke both rules.

A. The regulatory structure for approval of brand and generic drugs.

28. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

1. Approval pathways available to pharmaceutical products.

29. During the periods relevant here, section 505 of the Act described three pathways for approval of drug applications: (1) an application that contains full reports of

investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)).

a. Approval of new drugs under section 505(b)(1).

30. Under the FDCA, the manufacturer of a new drug must obtain FDA approval to sell the drug by submitting a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must contain scientific data demonstrating that a drug is safe and effective. New drug applicants, however, are not required to, and usually do not try to, show that their new drug product is superior to another similar, already approved product.

31. After FDA approval, the NDA holder may list in the Orange Book any patents that (i) claim the drug or a method of using the drug, and (ii) reasonably could be asserted against a would-be competitor seeking to make, use, or sell a competing version of the brand drug. If patents issue after approval, the manufacturer may list them in the Orange Book within 30 days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

32. The FDA relies completely on the brand manufacturer's truthfulness about whether a patent claims the drug product or a method of using the drug product and about whether an infringement claim could reasonably be asserted against a competitor – i.e., whether the patent is valid, enforceable, and actually claims the NDA product or a method of using it. The FDA does not have the resources, specialization, or legal authority to verify the

manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA performs merely a ministerial act.

b. Approval of generic drugs under section 505(j).

33. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments added to the FDCA two pathways to approval intended to expedite the availability of lower-cost alternatives to expensive brand drugs – one for generic products, and one for brand products.

34. First, the Hatch-Waxman Amendments simplified the regulatory process for generic manufacturers. Previously, generic applicants had to follow the same steps as an applicant filing an NDA, including costly and time-consuming clinical trials to establish safety and efficacy. This delayed approval of generic drugs or deterred companies entirely from manufacturing generic drugs, and deprived drug purchasers of the benefit of generic competition.

35. But under the Hatch-Waxman Amendments, a manufacturer seeking approval to sell a bioequivalent generic version of a brand drug can file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA filer only needs to show that its generic drug is bioequivalent to the brand drug. Bioequivalence means that the generic product delivers the same amount of the same active ingredient into a patient's blood stream for the same amount of time as does the corresponding brand drug, and hence has the same clinical effect. 21 U.S.C. § 355(j)(8)(B).

36. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products are therapeutically equivalent and may therefore be substituted for one another.

c. Approval of drugs under section 505(b)(2).

37. Second, the Hatch-Waxman Amendments permitted brand drug companies to streamline the NDA process by relying on already-conducted scientific studies, rather than incurring the expense and burden of redoing the studies from scratch. This is the third pathway for drug approval – through section 505(b)(2) of the Act. Section 505(b)(2) may be seen as an amalgam of section 505(b)(1) NDAs and section 505(j) ANDAs.

38. A 505(b)(2) application is a new drug application (NDA). But, unlike 505(b)(1) drug applications, applications submitted under this pathway need not contain voluminous, expensive studies and data developed by the drug sponsor.

39. Section 505(b)(2) expressly permits FDA to rely, for approval of an NDA, on data not developed by the applicant.[1] A 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." 21 U.S.C. 355(b)(2). So the FDA may to look to studies conducted on an already-approved brand product to support approval of a new NDA.

40. When the applicant seeks to use studies from another product, reliance on that information (whether a previously approved product or from published literature) must be scientifically appropriate. An applicant needs to provide a scientific "bridge" to demonstrate the

[1] Sections 505(b)(2) and (j) together replaced FDA's paper NDA policy, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products. *See* 46 Fed. Reg. 27,396 (May 19, 1981).

relationship of the referenced and proposed products. For example, the applicant may conduct bioavailability or bioequivalence studies to establish a bridge and establish that the proposed product is a pharmaceutical alternative.

41. Pharmaceutical alternatives are drug products that contain the identical therapeutic ingredient, but not necessarily in the same amount, dose, or form. A pharmaceutical alternative is held to the same standards of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates. 21 C.F.R. § 320.1(d).

42. Generally, any differences in rate and extent of absorption should be reflected in the labeling of the 505(b)(2) product. The proposed product does not need to be shown to be clinically better than the previously-approved product. Nor does it need to be bioequivalent. A section 505(b)(2) application would be appropriate for a controlled-release product that is not bioequivalent to an already-approved drug where the proposed controlled-release product is at least as bioavailable as the approved product, or where the pattern of release of the proposed product is at least as favorable as the approved pharmaceutically equivalent product.

43. In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to establish a fourth pathway for FDA drug approval for "biosimilar" drugs. But this pathway is available only if the brand biologic product is approved, or "licensed," under the Public Health Service (PHS) Act. Insulin products, including insulin glargine, have always been approved under the FDCA, not the PHS. So this pathway to approval has no applicability here. Nevertheless, biologics approved under the FDCA, like insulin glargine, enjoy the same efficiencies of approval as biosimilars under the 505(b)(2) pathway. *See* § 7002(e) of the Affordable Care Act (ACA). So the 505(b)(2) pathway, while largely used to obtain approval of

small-molecule drugs, has been used on several occasions to obtain approval of biologics that are similar to the reference product and marketed as biosimilars in Europe.

2. The intersection of drug-approval laws and the patent laws.

a. Requirements for submitting patent information.

44. Section 505(b)(1) of the FDCA and FDA regulations require that a sponsor of an NDA submit to the FDA a list of patents claiming either the approved drug substance or drug product or an approved method of using the drug product described in the NDA.

45. Specifically, section 505(b)(l) of the Act requires NDA applicants to file as part of the NDA,

> the patent number and the expiration date of any patent which claims the drug *for which the applicant submitted the application* or which claims a method of using *such drug* and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[2]

46. If an NDA applicant obtains additional patents that claim the drug or a method of using the drug after its NDA obtains approval, section 505(c)(2) requires the prompt submission of that patent information.[3]

47. The statutory language did not change during the time periods relevant to this complaint.

48. In October 1994, the FDA issued final rules addressing the submission of patent information. The rule clarified that a statutory language referring to patents "which claim[]

[2] 21 U.S.C. § 355(b)(l) (emphasis added).

[3] 21 U.S.C. § 355(c)(2) (emphasis added) ("If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent *which claims the drug for which the application was submitted* or *which claims a method of using such drug* and with respect to which *a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.").

the drug" or "a method of using such drug" are "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,344 (Oct. 3, 1994) (new and final rule publishing text of newly created § 314.53, "Submission of patent information," and responding to comments regarding that section) (emphasis added). The FDA admonished that "[f]or patents that claim a drug substance or drug product, the applicant shall submit information *only* on those patents that *claim a drug product that is the subject of a pending or approved application*, or that claim a drug substance that is a component of such a product." And it admonished that, for method-of-use patents, "the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application." *Id.*

49. The rule set forth the patent information a drug sponsor must provide, including "the type of patent, i.e., drug, drug product, or method of use" and the patent's expiration. 21 C.F.R. § 314.53(c)(1).

50. The rule also required a specific declaration for formulation, composition, and/or method-of-use patents stating: "The undersigned declares that Patent No. _____ covers the formulation, composition, and/or method of use *of (name of drug product)*. This product is (currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act) [or] (the subject of this application for which approval is being sought): _____." *Id.* at § 314.53(c)(2)(i). The declaration had to be signed by "the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative) or other authorized official." *Id.* at § 314.53(c)(4).

51. During its rulemaking, the FDA considered and rejected the argument that the FDCA required NDA applicants to provide only patent numbers and patent expiration dates.

The FDA explained that requiring additional patent information was consistent with the purposes of the Act, particularly in light of the FDA's lack of patent expertise:

> FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. Therefore, the agency declines the comment's requests to ensure that patent information is complete and relevant to an NDA and to confirm, upon request, the validity of patent information submitted to the agency. The agency believes that the declaration requirements under § 314.53(c), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted.[4]

52. The FDA likewise considered and rejected a comment suggesting that there was no need to identify a patent according to whether it claimed a formulation, composition, or method-of-use – that comment "suggested deleting the proposed rule's classification of patents and replacing it with a general certification that the patents listed by the applicant contain claims with respect to which the applicant could reasonably assert a claim of infringement . . . ." The FDA concluded that NDA applicants should identify which claims cover the drug or drug product and which claims cover a method of use:

> *FDA acknowledges that a patent may contain a variety of claims*, and has revised proposed § 314.53(c)(2) by creating a single certification statement . . . . However, because section 505(b)(1) of the act specifically requires applicants to 'file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application *or* which claims a method of using such drug,' and because FDA lacks patent law expertise, the agency strongly encourages applicants to identify, to the best of their ability, the type of patent covering the drug or drug product. This information will help FDA determine *which claims cover the drug or drug product and which claims cover a method of use.*[5]

53. Elsewhere in the commentary accompanying the amendment, the FDA stated:

[4] Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,345 (Oct. 3, 1994) (new and final rule).

[5] *Id.* at 50,343-44.

> FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better utilized in reviewing applications rather than reviewing patent claims.[6]
>
> The requirement in § 314.53(b) and (c) that applicants provide information on the type of patent … is consistent with the purpose of section 505(b)(1) of the act.[7]
>
> The statute expressly requires applicants to file 'the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application . . . ' (section 505(b)(1) of the act). Thus, if the formulation patent claimed the drug product in the application, the applicant must file information on that patent.[8]

54. On June 18, 2003, the FDA amended § 314.53 "to help ensure that NDA applicants submit only appropriate patents."

55. In short, the statute sets forth a two-part test: the patent must both (i) claim "the drug . . . or . . . a method of using such drug," and (ii) be such that "a claim of patent infringement could reasonably be asserted" against a proposed competitor product. NDA applicants are on their honor to properly identify the "[t]ype of patent, *i.e.*, drug, drug product, or method of use."[9] And the patent's drug product claim could claim not just some drug product – it had to claim the relevant drug product, i.e., the FDA-approved drug product as to which the NDA applicant listed the patent. NDA applicants were on their honor to properly identify the "Type of patent, *i.e.*, drug, drug product, or method of use."[10]

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[6] *Id.* at 50,343.

[7] *Id.*

[8] *Id.* at 50,344.

[9] 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).

[10] 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).

b. Requirements for patent certifications.

56. A drug product with an effective approval under section 505(c) of the Act is known as a *listed drug*.

57. As described above, the Act permits submission of 505(b)(2) or 505(j) applications for follow-on or generic versions of listed drugs. Both processes shorten the time and effort needed for approval by, among other things, allowing applicants to rely on the FDA's previous finding of safety and effectiveness for a listed drug. Each applicant must identify the listed drug on which it seeks to rely for approval.

58. The timing of 505(b)(2) and ANDA approvals depends on, among other things, the intellectual property protections for the listed drug that the 505(b)(2) or ANDA application references and whether the applicant challenges those protections (see sections 505(b)(2), (c), (j)(2)(A)(vii), and (j)(5)(B) of the Act).[11] In general, a would-be competitor who has submitted a 505(b) application or ANDA may not obtain final approval until listed patents and any marketing exclusivity have expired or until NDA holders and patent owners have had the opportunity to defend relevant patent rights in court.

59. With respect to each patent submitted by the sponsor and listed in the Orange Book for the listed drug, a 505(b)(2) applicant generally must submit to FDA one of four specified certifications under section 505(b)(2)(A) of the Act. The certification must state one of the following.

> (I) That the required patent information relating to such patent has not been filed (paragraph I certification).
>
> (II) That such patent has expired (paragraph II certification).

[11] Relevant intellectual property protections affecting the timing of ANDA approval include marketing exclusivity and listed patent protection for the listed drug. Marketing exclusivity is not at issue here.

> (III) That the patent will expire on a particular date (paragraph III certification).
>
> (IV) That such patent is invalid or will not be infringed by the drug for which approval is being sought (paragraph IV certification).

60. The purpose of these certifications is "to give notice, if necessary, to the patent holder so that any legal disputes regarding the scope of the patent and the possibility of infringement can be resolved as quickly as possible." *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003).

61. If an applicant files a paragraph I or II certification, the patent in question will not delay application approval. If an applicant files a paragraph III certification, the applicant agrees to wait until the relevant patent has expired before seeking full effective approval of its application.

62. If the patent has not expired, but the applicant believes its product does not infringe any valid listed patent, a paragraph IV certification may be filed as to substance or formulation patents. (Product method-of-use claims have special procedures not relevant here).

c. Paragraph IV litigation and 30-month stays.

63. As described, a 505(b)(2) applicant may seek FDA approval before expiry of all Orange Book listed patents by filing a paragraph IV certification stating that a listed patent "is invalid or will not be infringed by the manufacturer, use, or sale of the [applicant's] drug." 21 U.S.C. 355(b)(2).

64. The applicant filing a paragraph IV certification must also provide notice to the NDA holder and the patent owner stating that it has submitted an ANDA with a paragraph IV certification and explaining the factual and legal bases for the applicant's opinion that the patent is invalid or not infringed (see section 505(b)(2)(B) and (j)(2)(B) of the Act).

65. Filing a paragraph IV certification provokes litigation. The patent statute treats such filing as an act of technical infringement and provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the patent owner or NDA holder brings a patent infringement suit against the 505(b)(2) applicant within 45 days of the date it received notice of the paragraph IV certification, the approval of the 505(b)(2) application will automatically be stayed for 30 months, or less if the patent litigation is resolved sooner. *See* FDCA §§ 505(c)(3)(C) & (j)(5)(B)(iii). When the 30 months have expired, the patent ceases to be a barrier to final FDA approval, even if the patent litigation is ongoing. Similarly, if the patent owner or NDA holder receives notice of a paragraph IV certification and does not sue within 45 days of receipt of notice, the patent will not be a barrier to FDA final approval.

66. If the branded drug manufacturer initiates a patent infringement action against its would-be competitor within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the 505(b)(2) applicant's product.

67. Until one of those conditions occurs, the FDA may grant "tentative approval" but cannot grant "final approval," which would authorize the 505(b)(2) applicant to market its product. The FDA may grant a 505(b)(2) application tentative approval when it determines that the application would otherwise be ready for final approval were it not for the regulatory 30-month stay. Tentative approval is granted only when the applicant satisfies all scientific and procedural preconditions to final approval.[12]

[12] *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19-21 (D.D.C. 2004) ("Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform."); 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB) ("A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application."); 21 C.F.R. § 314.107(b)(3)(v) ("Tentative approval of an application does not constitute

68. At bottom: under the procedures established in the Hatch-Waxman Amendments, a 505(b)(2) application will not be approved until all listed patents: (1) have expired; (2) have been subject to a paragraph IV certification pursuant to which the patent owner or NDA holder has declined to sue within 45 days; or (3) have been subject to a paragraph IV certification that led to a lawsuit and either (i) a decision favorable to the applicant was reached, or (ii) the automatic 30-month stay that issued upon the filing of suit has expired.

B. The effect of follow-on biologics or generic drugs on competition.

69. *Competition from ANDA-approved generics.* The introduction into the market of generics approved under 505(j) as AB-rated generics to the reference branded product works dramatic, well-documented impacts on the sales and price of the product – generic penetration is rapid and thorough, price drops dramatically, and overall brand sales nearly vanish.

70. Due to the price differences between brand and generic drugs, and other institutional features of the pharmaceutical industry, the launch of a generic product results in the rapid shift of purchasers from brand to generic. Pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the brand drug. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for brand drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

71. Thus, once a generic hits the market, it quickly erodes the sales of the corresponding brand drug, often capturing 80% or more of the market within the first six

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'approval' under FDCA "and cannot, absent a final approval letter from the agency, result in an effective approval.").

months after launch and 90% of the brand's unit drug sales after a year. This results in dramatic savings for drug purchasers. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.

72. *Competition from 505(b)(2)-approved biologics or biosimilar products.* Follow-on biologics and biosimilar drugs are newer to the U.S. marketplace: the first one entered the market in 2015. The impact on sales, price, and penetration are therefore less understood than the nearly ubiquitous information about ANDA-approved generics. And there are differences in distribution, substitution laws, and prescription writing that make a direct analogy to ANDA-approved generics incomplete.

73. However, numerous studies have been issued estimating the cost savings (determined by estimated price reductions, penetration, and the like) on the introduction of follow-on biologics and biosimilar drugs.

74. A 2014 study by the Rand Corporation canvassed existing studies estimating the impact of the introduction of biosimilar products in the U.S. on price, absorption, and overall savings from the introduction of biosimilars. Combining the results of these studies, Rand estimated overall biosimilar market penetration of 60 percent and a biosimilar price discount due to competition of 35 percent. For the insulin market itself, Rand assumed 100 percent of the established insulin and growth hormone markets would be exposed to biosimilar competition in the next year (i.e., 2015, but that would turn out not be, due to Sanofi's unlawful conduct to stall Lilly's entry), but with half the biosimilar penetration and price discounts of other markets. It observed that while the 35 percent price reduction estimate was on the high end of those included in the models it had analyzed, it acknowledged that the Congressional

Budget Office had anticipated an even larger 40 percent reduction in the long term. All studies reviewed by Rand anticipated some amount of substantial price decreases from biosimilar entry.

C. Brand manufacturers can employ multiple tactics to block follow-on competition.

75. Competition from lower-priced follow-on competitor drugs saves drug purchasers billions of dollars a year. These savings, however, mean lower profits for brand drug companies. Brand manufacturers thus seek to extend their monopolies for as long as possible, sometimes resorting to any means possible – including illegal means.

76. First, brand manufacturers can game the system by listing in the Orange Book patents that do not in fact claim the drug product. Because the FDA performs merely a ministerial task in listing a patent in the Orange Book, the patent-listing system is easily manipulated by brand companies.

77. In July 2002, the Federal Trade Commission ("FTC") published a study that reported on the growing industry trend for brand manufacturers to prevent or delay the marketing of generic drugs by submitting inaccurate or improper patent information to the FDA for listing in the Orange Book. *See* FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* at iii-vi (July 2002).

78. The FTC report cited one case wherein a brand company facing patent expiration listed a new patent with the FDA in order to extend its right over the drug. Relying on the brand company's representation and unaware that the new patent listing, in fact, covered neither the drug's compound nor any method of using it, the FDA declined to approve the generic drug. In response, the generic ANDA applicant sued to remove the improper Orange Book patent listing, but the Federal Circuit found that it had no such right of action under Hatch-Waxman. Thus, the generic manufacturer's only option was to file a paragraph IV certification of noninfringement that immediately triggered the infringement suit and forced

the generic to wait out the statutorily prescribed 30-month stay of ANDA approval by the FDA. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

79. To address these anticompetitive abuses, Congress authorized generic manufacturers in patent infringement suits to assert a legal counterclaim challenging the brand manufacturer's submission of patent information to the FDA. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2452. The applicable provision states that an applicant sued for patent infringement "may assert a counterclaim seeking an order requiring the [brand company] to correct or delete the patent information submitted" by the brand company "on the ground that the patent does not claim either (aa) the drug for which the [brand company's NDA] was approved; or (bb) an approved method of using the drug." 21 U.S.C. § 355(j)(5)(c)(ii)(1).

80. This statutory amendment provides recourse to a would-be competitor for improper patent information that is blocking FDA approval of its application. But it does not avoid delays in approval.

81. Second, branded drug manufacturers can game the system by describing patents as containing drug product claims (even if the patents, in fact, do not do so), and then suing a would-be competitor that files a paragraph IV certification, even though that lawsuit lacks all merit (i.e., even if the competitor's product does not actually infringe any properly-listed patent). Regardless of merit, filing of the suit delays final FDA approval of a 505(b)(2) application for up to 30 months.

82. Simply by suing on an Orange-Book-listed patent within 45 days (even if the patent should not have been listed or was misidentified, and even if the suit would likely fail if ever permitted to go to an ultimate conclusion), the brand manufacturer automatically prevents the FDA from granting final approval to the would-be competitor's application until the earlier

of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the competitor's application.

83. That branded drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay drug competition – as opposed to enforcing a valid patent that is actually infringed by the competitor's drug – is demonstrated by the fact that, in 73% of the paragraph IV litigation cases studied, the brand company lost on the merits or was forced to dismiss the suit.

V. FACTS

A. Diabetes: a deadly but treatable disease.

84. The number of Americans who live with diabetes has exploded in the last half century. In 1958, only 1.6 million people in the United States had diabetes. By the turn of the century, that number had grown to over 10 million. Just 14 years later, the headcount tripled again. Now over 29 million people – 9.3 percent of the country – live with the disease. And this trend does not appear to be slowing: 86 million Americans have prediabetes, a health condition that significantly increases a person's risk of type 2 diabetes.

85. Diabetes occurs when a person has too much glucose – sugar – in her bloodstream. A lack of insulin or diminished responsiveness to insulin causes the process to break down, leading to high blood sugar levels. If left unchecked, high blood sugar levels lead to diabetes.

86. There are two basic types of diabetes. Ninety to ninety-five percent of Americans living with diabetes developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce. Known as type 2, this more common form of diabetes is typically associated with increased body weight and is often developed later in life. In contrast, type 1 diabetes occurs when a patient completely ceases

insulin production. This form of diabetes is usually diagnosed in children and young adults, but can occur at any age.

87. If left untreated or under-treated, diabetes is debilitating, and potentially deadly: it remains the seventh leading cause of death in the United States, despite the availability of effective treatments. But despite its potential lethality, diabetes is very treatable.

B. Insulin: a century of patent protection.

88. An effective treatment for diabetes has been available for almost a century.

1. Insulin's unselfish beginnings.

89. In 1922, two men – orthopedic surgeon Frederick Banting and medical student Charles Best – pioneered a technique for removing active insulin from an animal pancreas for injection into humans with diabetes.

90. Banting and Best's discovery was striking, and not only because it represented a medical breakthrough. At first, neither Banting nor Best applied for a patent on their game-changing innovation because they wanted their discovery to be open to the public, available to all for use. When the two eventually did patent the drug, it was only to protect its availability to the public: Banting and Best realized that if they did not patent their drug, someone else would. They sold their insulin patent to the University of Toronto for $1 each, hoping to ensure that, "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[13]

91. University of Toronto researchers teamed up with Eli Lilly, and agreed that Lilly could apply for U.S. patents on any manufacturing process improvements. They reached similar agreements with a few other companies, including Denmark's Nordisk

[13] Michael Bliss, *The Discovery of Insulin* (2d ed. 2007).

Insulinlaboratorium and Novo Terapeutisk Laboratorium, two companies that later merged to form Novo Nordisk.

92. Flouting Banting and Best's intentions, those companies quickly set to work shielding insulin behind a wall of patents. Over the next 90-plus years, pharmaceutical researchers sought to secure and extend a monopoly in the insulin market. Research spawned multiple types of insulin – animal insulin, long-acting animal insulin, human insulin, analogue insulins, rapid-acting analogue insulins, and long-acting insulins – each shielded by layers of patents licensed to pharmaceutical companies that had forgotten the generosity of Banting and Best.

2. Animal insulin: the insulin patent parade begins.

93. The original animal insulin was short acting – it only had an effect on patient blood sugar levels for three to six hours. In the early 1930s, however, scientists at Nordisk created long-acting animal insulin. In 1946, researchers added zinc to form the crystalline protamine-isophane insulin, now known as neutral protamine Hagedorn (NPH), making it possible to combine long-acting and short-acting insulin into one product and allowing many diabetes patients to take a single daily injection. Soon afterward, a method for prolonging the action of insulin without adding protamine was discovered. These innovations offered important new options for the dosing of insulin. But they also extended the reach of insulin patents into the 1970s.

3. Human insulin.

94. In the late 1970s, just as these animal-based insulin patents were expiring, researchers began to produce human insulin through recombinant technology. By 1982, Eli Lilly brought the first recombinant human insulins to the U.S. market.

95. Around the same time, Novo and Nordisk developed methods for chemically converting bovine insulin into human insulin. The advent of these new human insulins also enabled Lilly and Novo/Nordisk to spin a fresh web of insulin patents, which stretched into the 21st century.

4. Rapid-acting insulin analogues.

96. In the mid-1980s, scientists learned to modify the molecular structure of insulin and improve its physiological effects. By 1996, Eli Lilly had obtained approval for the first rapid-acting, manmade insulin. This new type of insulin – known as an analogue – allowed for substantially faster absorption. Never far behind Lilly, Novo Nordisk released its own analogue in 2000.

97. Four years later, Sanofi entered the insulin-patent game, releasing another rapid-acting analogue. Another round of patents over these new products further extended these three companies' monopoly over insulin markets.

5. Long-acting insulin analogues.

98. In 2000, Sanofi released the first long-acting analogue. This drug was branded as Lantus (insulin glargine). Five years later, Novo Nordisk gained approval for its own long-acting analogue, Levemir (insulin detemir). The main patents on these long-acting products expired in June 2014, nearly a century after Banting and Best's first patent application in 1923.

99. Insulin glargine and insulin detemir are not the same product. While both are basal insulin formulas (i.e., they last for a long time in the body and act as background insulin, with a slow feed that mimics the constant low output of insulin produced by a healthy pancreas), they are also differentiated.

100. Insulin glargine (marketed until mid-December 2016 as only Lantus and Lantus SoloSTAR) is a clear formula made with glargine, a genetically modified form of human insulin,

dissolved in a special solution. Human insulin is made of two amino acid chains, called A and B, that have two disulfide bonds between them. In glargine, one amino acid has been switched out, and two extra amino acids have been added to one end of the B chain. The modifications make glargine soluble at an acidic pH, but much less soluble at the neutral pH that is found in the body.

101. Before it is injected into the body, insulin glargine is maintained completely dissolved in an acidic solution: it is produced by a vat of E. coli bacteria, then purified and added to a solution containing zinc and glycerol; hydrochloric acid is then added, resulting in the solution having a pH of about 4. When injected into subcutaneous tissue, the acidic insulin glargine solution meets an environment with a neutral pH. Because glargine is not soluble at a neutral pH, it precipitates, or falls out of its watery solution, and becomes relatively insoluble. Small amounts slowly move back into solution over time and then to the bloodstream, making the product long-acting.

102. Insulin detemir works differently. Like insulin glargine, it is formed through recombinant DNA technology, but it is produced by baker's yeast instead of E. coli. Like insulin glargine, some amino acids in the molecule have been replaced. But instead of being replaced with different amino acids, insulin detemir's amino acid is substituted with a fatty acid. Manitol is used instead of glycerol. And insulin detemir may be made acidic using sodium hydroxide instead of hydrochloric acid. Unlike insulin glargine, insulin detemir does not form a precipitate upon injection. Instead, insulin detemir's molecules stick to one another when injected into a neutral-pH environment, so it is slowly absorbed. Once the detemir molecules dissociate from each other, they readily enter the bloodstream, where the added fatty acid binds to albumin. More than 98 percent of detemir in the bloodstream is bound to albumin. With

the albumin stuck to it, the insulin cannot function. Because it slowly dissociates from the albumin, it is available to the body over an extended period.

103. Insulin glargine and insulin detemir are different molecules and are not reasonably interchangeable. Because insulin glargine achieves its long-acting effect through insolubility in the human body, while insulin detemir achieves a similar effect through its binding properties (first to itself, then to albumin), the drugs have different mechanisms of action. And insulin glargine is, obviously, not equivalent to animal insulin, human insulin, or the rapid-acting human insulin analogues.

C. The compound patent for insulin glargine.

104. In August of 1997, the Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,656,722 ("the '722 patent") for insulin glargine to a German inventor. Exhibit A to this complaint is a copy of the '722 patent. The patent was assigned to Hoechst AG, a German chemicals life-sciences company that became Aventis Deutschland after a merger with France's Rhône-Poulenc S.A. in 1999. With the new company's 2004 merger with Sanofi-Synthélabo, it became a subsidiary of the resulting Sanofi-Aventis pharmaceuticals group.

105. The '722 patent claimed insulin glargine and also disclosed the addition of zinc, m-cresol, glycerol, water, and pH adjusted by solutions of hydrochloric acid (HCl) and sodium hydroxide (NaOH), as used in the Lantus formulations approved by the FDA in April 2000. Ex. A, col. 5, ll. 32-40, 47, 52-57.

106. The '722 patent expired on August 12, 2014. Pursuant to FDA regulation, Sanofi earned an additional period of pediatric exclusivity extending to February 12, 2015.

D. The approval of Lantus, the first insulin glargine injection.

107. On or about April 20, 2000, the FDA approved NDA No. 21-081 for Lantus (insulin glargine [rDNA origin] injection).

108. Sanofi listed the '722 patent in the Orange Book.

109. Lantus is a sterile solution of insulin glargine for use as an injection.

110. As first approved, Lantus was indicated for once-daily subcutaneous administration at bedtime in the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. Its potency is approximately the same as human insulin, and it exhibits a relatively constant glucose-lowering profile over 24 hours that permits once-daily dosing.

111. When Lantus was approved by the FDA in April 2000, it had two package forms: (1) vials (5 and 10 mL) for use with single-dose syringes, and (2) cartridges (3 mL) for use in an injector pen Sanofi called "OptiPen™ One." Different pens are marketed for use by diabetic patients to inject their insulins.

112. Sanofi U.S. is the holder of NDA No. 21- 081.

113. Sanofi possesses a copy of NDA No. 21-081 and any supplements and amendments thereto, and it possesses a copy of the communications with the FDA regarding approval by the FDA of NDA No. 21-081 and any supplements and amendments thereto.

114. Sanofi U.S. possesses documents evidencing the identity of the active and inactive ingredients of the insulin glargine [rDNA origin] injection products that have been prescribed and sold in the United States under NDA No. 21-081.

115. The FDA's letter approving NDA No. 21-081 included the following statement: "The final printed labeling (FPL) must be identical to the submitted draft labeling ((1) package insert submitted April 20, 2000, (2) patient package inserts [for vials and cartridges] submitted April 20, 2000, (3) OptiPen One User Manual dated April 18, 2000, and (4) immediate

container and carton labels [for 5 mL and 10 mL vials and 3 mL cartridges] submitted April 18, 2000)."

116. The draft package insert for NDA No. 21-081 having a date of submission of April 20, 2000, included the following statement: "Each milliliter of LANTUS (insulin glargine injection) contains 100 IU (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection. The pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide."

117. Exhibit B to this complaint is a copy of the draft package insert for NDA 21-081 bearing a date of submission of April 20, 2000.

118. At some point on or about the time of approval of Lantus, Sanofi caused the '722 patent to be listed in the Orange Book. Over the years, the Orange Book identified Lantus as a single product made in two formulations: "injectable" (i.e., the "vial formulation," which was initially sold in 5 mL and 10 mL amounts), and "injection" with an OptiClick injector pen (i.e., the "cartridge formulation"). The listing of the '722 patent did not distinguish between the two formulations (as the '722 patent claimed the drug substance and drug product contained in both).

E. The launch and sale of Lantus.

119. After approval by the FDA of NDA No. 21-081, in May 2001, Lantus was launched for sale in the United States. Lantus was prescribed and sold in the United States from May 2001 through the present.

120. Each milliliter of Lantus prescribed and sold in the United States at times after approval by the FDA of NDA No. 21-081 (including the period before September 9, 2001) contained 100 IU (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol

85%, and water for injection, and the pH was adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide.

121. From the launch of Lantus in May 2001 through to February 2015, sales of the product were protected by the '722 patent and its listing in the Orange Book. As a result, the sales of Lantus were protected for almost 15 years – from launch until February 2015 – from competition from generic or follow-on insulin glargine products.

122. This lawsuit does not challenge Sanofi's rights to charge supra-competitive prices for Lantus products up until February 2015. But it does challenge Sanofi's unlawful conduct in prolonging its exclusive position beyond February 2015, i.e., beyond the expiration of the '722 patent.

123. During Sanofi's period of lawful exclusivity, it realized staggering profits. In 2014 alone, U.S. gross sales for Lantus products were $7.87 billion.

F. The 2005 vial supplement.

124. In 2005, five years after Lantus was approved, Sanofi received FDA approval to add an ingredient, polysorbate 20, to the 10 ml Lantus vial formulation.

125. On March 15, 2005, the FDA approved Supplemental NDA No. 21-081/S-017 (the "2005 vial supplement"). Exhibit C to this complaint is a copy of the March 2005 supplemental approval.

126. The 2005 vial supplement provided for the addition of 20 ppm of polysorbate 20 to each 10 mL vial of Lantus (by this time, Sanofi had pulled the 5 mL option off the market).

127. The supplemental new drug application did *not* provide for the addition of polysorbate 20 to the 3 mL *cartridge* formulation of Lantus; the Lantus cartridge formulation for use in the OptiPen One injector pen remained unchanged.

G. The 2007 approval and launch of Lantus SoloSTAR.

128. In 2007, Sanofi received an approval from the FDA for a "package change" – allowing Sanofi to sell Lantus in another, disposable injector pen called SoloSTAR. Exhibit D to this complaint is a copy of the package change approval.

129. Each milliliter of Lantus SoloSTAR contains 100 Units (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection, and the pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide. It does *not* contain polysorbate 20.

130. With the addition of Lantus SoloSTAR, Lantus products were approved in three product formulations: the original 10 mL vials (NDC 0088-2220-33); the original 3 mL cartridge system using the OptiClik injector pen, package of 5 (NDC 0088-2220-52); and the new 3 mL SoloSTAR disposable insulin device, package of 5 (NDC 0088-2220-60). Only the vial formulation provided for the addition of 20 ppm of polysorbate 20; the other two did not.

H. The Lantus polysorbate vial formulation patents.

131. Back on September 9, 2002, two Sanofi scientists had filed a provisional application with the PTO seeking patent protection for a pharmaceutical formulation.

132. On January 13, 2009, the PTO issued U.S. Patent No. 7,476,652 ("the '652 patent"), entitled "Acidic Insulin Preparations Having Improved Stability." The '652 patent expires July 23, 2023, with a six-month period of pediatric exclusivity extending until January 23, 2024. A true and copy of the '652 patent is attached as Exhibit E to this complaint.

133. On May 11, 2010, the PTO issued U.S. Patent No. 7,713,930 ("the '930 patent"), entitled "Acidic Insulin Preparations Having Improved Stability." The '930 patent expires June 13, 2023, with a period of pediatric exclusivity extending to December 13, 2023. A true and copy of the '930 patent is attached as Exhibit F to this complaint.

134. By assignment, Sanofi GmbH owns all right, title, and interest in and to the '652 and '930 patents. It licenses exclusively to Sanofi U.S. all rights under the '652 and '930 patents, including the rights to sell and offer to sell in the United States the technologies, products, or services claimed by them. But neither Sanofi GmbH nor Sanofi U.S. has the right to assert rights in those patents beyond the scope of the claims contained in them.

135. The '652 and '930 patents set forth examples of an insulin glargine formulation in which polysorbate 20 or 80 was added. Ex. E, cols. 5-10; Ex. F, cols. 6-11. The patents claim a formulation requiring use of "polysorbate 20," "polysorbate 80," "polysorbate[s]" or "poloxamers."

136. The '652 and '930 patents are herein referred to as the "polysorbate vial patents."

137. Sanofi tried during prosecution of the '652 patent to obtain broader claims, but the patent examiner repeatedly rejected them over prior art. In the '930 patent, which has the same examples as the '652 patent, a different patent examiner allowed patent claims requiring use of "esters [or] ethers of polyhydric alcohols." The '652 patent examiner had specifically rejected this language as unpatentable.

138. Because the Lantus polysorbate vial formulation patents are based on applications filed in the U.S. on September 9, 2002, they are governed by the "pre-AIA" version of patent law. The "critical date" for prior art to these patents under 35 U.S.C. § 102(b) is therefore September 9, 2001. Section 102(b) prior art includes subject matter on sale or in public use in the U.S. before the critical date.

I. The polysorbate vial formulation patents do not cover the formulations for the Lantus cartridge or Lantus SoloSTAR.

139. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not polysorbate.

140. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not poloxamers.

141. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not esters of a polyhydric alcohol.

142. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not ethers of a polyhydric alcohol.

143. The cartridge formulation of Lantus does not contain a polysorbate.

144. The cartridge formulation of Lantus does not contain a poloxamer.

145. The cartridge formulation of Lantus does not contain an ester of a polyhydric alcohol.

146. The cartridge formulation of Lantus does not contain an ether of a polyhydric alcohol.

147. The cartridge formulation of Lantus is not within the scope of any independent claim of the '652 patent.

148. The 3 mL cartridge presentation of Lantus is not within the scope of any independent claim of the '930 patent.

149. Lantus SoloSTAR does not contain a polysorbate.

150. Lantus SoloSTAR does not contain a poloxamer.

151. Lantus SoloSTAR does not contain an ester of a polyhydric alcohol.

152. Lantus SoloSTAR does not contain an ether of a polyhydric alcohol.

153. Lantus SoloSTAR is not within the scope of any independent claim of the '652 patent.

154. The Lantus SoloSTAR product is not within the scope of any independent claim of the '930 patent.

J. Sanofi's wrongful listing of the polysorbate vial formulation patents.

155. Following the issuance of each of the polysorbate vial formulation patents, Sanofi listed the '652 patent and the '930 patent to be identified in the Orange Book as indiscriminately claiming "LANTUS" in all of its product formulations, both vial and cartridge.

156. Under the Hatch-Waxman Act and applicable regulations, the FDA requires that an NDA holder submit information identifying *only* a "patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

157. The '652 patent and the '930 patent only arguably claim the vial formulation of Lantus (as now modified to add the polysorbate). They do not claim Lantus in its cartridge formulations, i.e., the original Lantus OptiClik injector pen and the Lantus SoloSTAR disposable insulin device. So they should not have been identified in the Orange Book as applicable to the two cartridge formulations of Lantus.

158. However, when providing information to the FDA, Sanofi did not clearly delineate the scope of the '652 and '930 patents. It falsely and misleadingly indicated to the FDA that both patents covered the two injector formulations.

159. The this wrongful listing of the '652 patent and the '930 patent in the Orange Book as covering the Lantus cartridge formulations persisted through the 33rd edition (2013) of the publication.

K. Sanofi collects injector pen patents.

160. In or around 2013, Sanofi – in an effort to build a portfolio to block competition to its Lantus franchise – began to collect a series of injector pen patents.

161. In March 2003, a design company called DCA Design International, Ltd. from Warwick, England filed a British patent application directed to a particular approach to an injector pen. That application spawned numerous different continuing applications, resulting in various patents.

162. On April 5, 2011, United States Patent No. 7,918,833 ("the '833 patent"), entitled "Pen-Type Injector" was issued by the PTO. The '833 patent expires September 23, 2027, with a period of pediatric exclusivity extending to March 23, 2028. A true and copy of the '833 patent is attached as Exhibit G to this complaint.

163. On August 20, 2013, United States Patent No. 8,512,297 ("the '297 patent"), entitled "Pen-Type Injector" was issued by the PTO. The '297 patent expires September 15, 2024. A true and copy of the '297 patent is attached as Exhibit H to this complaint.

164. On October 15, 2013, United States Patent No. 8,556,864 ("the '864 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices," was issued by the PTO. The '864 patent expires March 3, 2024. A true and copy of the '864 patent is attached as Exhibit I to this complaint.

165. On December 10, 2013, United States Patent No. 8,603,044 ("the '044 patent"), entitled "Pen-Type Injector," was issued by the PTO. The '044 patent expires March 2, 2024. A true and copy of the '044 patent is attached as Exhibit J to this complaint.

166. The '833, '297, '864, and '044 patents are herein called the "DCA injector pen patents." All of the DCA injector pen patents are based on DCA Design's one British patent application filed in March 2003.

167. In or before August 2013 for the '833 patent, and shortly after PTO issuance for the '297, '864, and '044 patents, Sanofi GmbH acquired all right, title, and interest in and to those patents, and Sanofi U.S. became an exclusive licensee of them.

L. Sanofi rearranges its Orange Book listings to create a patent roadblock to follow-on competition.

168. As explained above, section 505(b)(1) of the FDCA allows NDA holders to list *only* patents which "claim[] the drug" or "a method of using such drug," and only if "a claim of patent infringement could reasonably be asserted" against a would-be competitor. 21 U.S.C. § 355(b)(1). FDA regulation 21 C.F.R. § 314.53(b) (1999) & (2002) provides that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug* product that is the subject of a pending or approved application, or that claim a *drug* substance that is a component of such a product."

169. Patents claiming something *distinct* from the relevant drug product or drug substance (e.g., patents claiming only packaging or a container) "fall outside of the requirements of patent submission," and so must not be submitted. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, 36,680 (June 18, 2003). "However," the Agency continued, "we have clarified the rule to ensure that *if* the patent claims the *drug product as defined in § 314.3*, the patent must be submitted for listing . . . . The key factor is whether the patent being submitted claims the finished dosage form *of the approved drug product.*" *Id.* (emphasis added).

170. 21 C.F.R. § 314.3(b) defines a "drug product" as "a finished dosage form, for example, *tablet, capsule, or solution, that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients" (emphasis added).

171. The DCA injector pen patents claim specific form of a pen-type injector, or a dose indicator, drive mechanism or housing in specific forms for a pen-type injector.

172. The DCA injector pen patents do not claim a drug substance, a drug product, or a method of using a drug. The DCA injector pen patents are not drug substance patents (they claim no "active ingredient"), drug product patents (because they claim no "finished dosage form . . . that contains a drug substance"), or patents for a method of using a drug. And the DCA injector pen patents do not make a claim for "the drug for which the application was submitted," i.e., Lantus in its various pen injector formulations (nor, of course, for Lantus in its vial formulation).

173. Therefore, the DCA injector pen patents were not eligible to be listed in the Orange Book for any Lantus product.

174. Until the summer of 2013, Sanofi had identified a single product, Lantus, available in two formulations (vial and cartridge), in the FDA's Orange Book.

175. In or about August 2013, Sanofi for the first time split the listing in the Orange Book to reference two products under a single NDA: product 001 identifying "Lantus," and product 002 for "Lantus SoloSTAR." Exhibit K to this complaint is the Orange Book listing for insulin glargine 34th edition (2014). The Orange Book also continued to Lantus (now product 001) in two general formulations: "INJECTABLE" (i.e., the vial formulation), and "INJECTION" (i.e., the cartridge formulation).

176. With respect to product 001, Lantus, Sanofi sent patent information to the FDA causing it to list (1) the original '722 drug substance patent, (2) the vial formulation patents, and (3) the '833 DCA injector pen patent.

177. The '722 drug substance patent claimed both the vial and cartridge formulations of Lantus. But the vial formulation patents did not claim the Lantus cartridge formulation (because no polysorbate was added to the cartridges), so the vial formulation patents should not have been listed in the Orange Book as to the cartridge formulation. And the '833 DCA

injector pen patent did not claim the vial formation (because the vial formulation had no injector pen), so the '833 DCA injector pen patent should not have been listed in the Orange Book as to the vial formulation.

178. With respect to product 002, Lantus SoloSTAR, Sanofi did *not* list the vial formulation patents. Instead, Sanofi listed the original '722 drug substance patent and two DCA injector pen patents (the '297 and '864 patents) as claiming Lantus SoloSTAR. (Sanofi later added the other DCA injector pen patents to this list).

179. The '722 drug substance patent claimed the active ingredient in Lantus SoloSTAR. But the DCA injector pen patents did not claim a drug substance, drug product, or method of using a drug product. They should not have been listed in the Orange Book.

180. The only lawful listings available to Sanofi at the end of 2013 were (i) that the '722 patent as to Lantus and Lantus SoloSTAR (with expiry on August 12, 2014, and pediatric exclusivity through February 12, 2015), and (ii) that the vial formulation patents, as to the vial formulation of Lantus *only* (not the original 3 mL cartridge formulation with OptiClik injector pen, or the SoloSTAR disposable insulin device).

181. By wrongfully listing the other patents, by the end of 2013, Sanofi had created an unlawful Orange Book roadblock for would-be follow-on biologic competitors for the insulin glargine market. It had falsely and misleadingly listed the '652 and '930 vial formulation patents as ostensibly claiming the cartridge formulation of Lantus (even though Sanofi's FDA approvals did *not* provide for the addition of 20 ppm of polysorbate 20 to the 3 mL *cartridge* presentation of Lantus insulin glargine [rDNA origin] injection). And it had falsely and misleadingly listed the DCA injector pen patents as claiming Lantus SoloSTAR.

182. As a result, any would-be competitor seeking FDA approval to market (after expiration of the '722 patent in mid-February, 2015) a follow-on, injector pen formulation of

insulin glargine would be forced to file (unnecessary) paragraph IV certifications as to the vial formulation patents and the DCA injector pen patents. And Sanofi could then sue, triggering the 30-month statutory bar on final FDA approval to the competitor's application.

M. The October 2013 labeling revision.

183. In October 2013, the FDA approved a labeling revision for Lantus. Exhibit L hereto is a copy of the October 2013 revision of the Prescribing Information for Lantus.

184. Each milliliter of the 3 mL cartridge presentation referred to in section 11 of Exhibit L contains 100 units (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection, and its pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide.

185. The 2013 did not change the frivolity of Sanofi's Orange Book listings.

N. Lilly's effort to obtain approval to market insulin glargine for injection.

186. For several years, Lilly, one of the original leaders in insulin products worldwide, worked with Boehringer Ingelheim to develop a follow-on insulin glargine product having a similar safety and efficacy profile as Sanofi's Lantus and Lantus SoloSTAR.

187. Lilly filed an investigational new drug application and worked with the FDA on numerous aspects of the Lilly product. Among other things, Lilly had a scientific and business plan to use its KwikPen platform – an injector pen device approved by the FDA and used successfully for other, widely-used Lilly products for its insulin glargine product. After review, the FDA agreed that the KwikPen was a viable design for Lilly's insulin glargine and several other Lilly products. In doing so, the FDA noted that KwikPen insulin products have been marketed for a number of years without significant user problems or product quality issues.

188. In late 2013, Lilly filed with the FDA NDA No. 205-692, seeking approval to market insulin glargine [rDNA origin] for injection, 100 units/mL, in the U.S. The

application was submitted under § 505(b)(2) of the FDCA; it could not be submitted under the "biosimilar" approval pathway because Lantus had been approved under the FDCA, not the PHS.

189. Lilly relied in its application on safety and efficacy studies comparing Lantus to other human or rapid-acting insulin products, which concluded that Lantus's effect on blood glucose levels was comparable to that of human insulin. The safety and effectiveness of Lantus was compared to that of once-daily and twice-daily Basaglar in open-label, randomized, active-controlled, parallel studies of 2,327 adults and 349 pediatric patients with type 1 diabetes mellitus and 1,563 adult patients with type 2 diabetes mellitus. In general, the reduction in glycated hemoglobin (HbA1c) with Lantus was similar to that of Basaglar, meaning that Basaglar was "non-inferior" to Lantus. These studies established a "bridge" between Basaglar and Lantus to demonstrate that Basaglar was sufficiently similar to Lantus such that reliance on Lantus studies was scientifically justified. The Lantus data, together with product-specific data (including product-specific data demonstrating safety and effectiveness), established Basaglar's safety and effectiveness for its proposed uses. The composition, strength, and presentation of Basaglar were determined to be similar in composition, strength, and presentation to Lantus.

190. Basaglar did not use polysorbate, a poloxamer, or esters or ethers of polyhydric alcohols.

191. Because Basaglar did not use a polysorbate, a poloxamer, or esters or ethers of polyhydric alcohols, it did not infringe the vial formulation patents.

192. On December 18, 2013, Lilly sent a "Notice of Paragraph IV Certifications" to Sanofi, informing Sanofi that Lilly had filed an NDA pursuant to § 505(b)(2) to market the Basaglar. The December 18, 2013 notice letter addressed all patents listed in the Orange Book

for Lantus and Lantus SoloSTAR. Lilly filed a paragraph III certification as to the '722 patent, agreeing to wait to market its product until that patent expired. It filed paragraph IV certifications as to the vial formulation patents and DCA injector pen patents, certifying that those patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the Lilly NDA product.

193. In other words, Lilly sought approval to sell its insulin glargine injector product upon the February 15, 2015 expiration of Sanofi's insulin glargine patent and its pediatric exclusivity.

194. On December 19, 2013, Sanofi U.S. received Eli Lilly's Notice of Paragraph IV Certifications.

195. On December 20, 2013, Sanofi GmbH received Eli Lilly's Notice of Paragraph IV Certifications.

196. Meanwhile, Sanofi collected the additional '044 DCA injector pen patent and listed it in the Orange Book.

197. On January 23, 2014, Lilly sent an "Amended Notice of Paragraph IV Certifications," repeating its paragraph III certification as to the '722 patent and adding the '044 patent to the list of patents that Lilly claimed were invalid, unenforceable, or would not be infringed by Basaglar.

198. Both of Lilly's December and January submissions contained detailed statements analyzing the prosecution histories and claims of the Orange Book-listed patents and identified numerous limitations missing in Lilly's NDA product. Lilly's detailed statements warned that Lilly may defend any baseless lawsuits by asserting, among other things, patent misuse.

199. On January 24, 2014, Sanofi U.S. received Eli Lilly's Amended Notice of Paragraph IV Certifications.

200. On or about January 27, 2014, Sanofi GmbH received Eli Lilly's Amended Notice of Paragraph IV Certifications.

201. Lilly's December Notice of Paragraph IV Certifications was accompanied by an offer of confidential access.

202. On January 23, 2014, Lilly and Sanofi executed an offer for confidential access, entitled "Terms of Confidential Access."

203. On January 25, 2014, Sanofi received approximately 66 pages of Lilly's 505(b)(2) application. Those pages were provided subject to the agreed confidentiality and included an identification of the active and inactive ingredients of the formulation of Basaglar.

204. Sanofi did not request any further information regarding the formulation of Basaglar, and so none was provided.

205. The pages of from Lilly's 505(b)(2) application (i) showed the list of ingredients of Lilly's NDA product, and (2) identified the type of injector pen by which the Lilly NDA product would be administered. The documents showed that the Lilly NDA product would not infringe any of the claims the two injector pen patents (the '864 and '044 patents) or any claims in the two vial formulation patents (the '652 and '930 patents).

O. The Sanofi lawsuit.

206. On January 30, 2014 – just three days after its receipt of Lilly's documents – Sanofi sued Lilly on the '652 and '930 vial formulation patents and the '044 and '864 DCA injector pen patents. The action was brought in the United States District Court for the District of Delaware, bearing civil action number 14-113 (the *"Sanofi I"* litigation).

207. Sanofi commenced *Sanofi I* within 45 days of receiving Lilly's notice letter. As a result – and despite the absence of any merit to the claims of infringement – Sanofi obtained an automatic 30-month stay of FDA approval of Basaglar. Absent an earlier ruling form the

district court, the FDA now was statutorily barred from granting Lilly final approval for Basaglar until May 16, 2016.

208. Sanofi alleged in its complaint that it has "listed each of the '864, '044, '652, and '930 Patents in the Orange Book as covering its Lantus® and/or Lantus® SoloSTAR® products."

209. That statement was misleading. In fact, the '652 and '930 vial formulation patents were only listed as claiming Lantus, and the '044 and '864 pen patents were only listed as claiming Lantus SoloSTAR.

210. Sanofi sued Lilly with respect to the '652 vial formulation patent even though, after reviewing the materials provided by Lilly, its lawyers had no basis to conclude that the formulation of Basaglar is covered by any claim of the '652 patent.

211. Sanofi sued Lilly with respect to the '930 vial formulation patent even though, after reviewing the materials provided by Lilly, its lawyers had no basis to conclude that the formulation of Basaglar is covered by any claim of the '930 patent.

212. The 66 pages of documents produced by Lilly pursuant to the Terms of Confidential Access included an identification of the particular injector device that would be used with the Lilly NDA product. Sanofi did not request from Lilly more information regarding Lilly's injector device.

213. Sanofi sued Lilly with respect to the '864 DCA injector pen patent even though, after reviewing the materials Lilly provided, its lawyers had no basis to conclude that Lilly's KwikPen was covered by any claim of the '864 patent.

214. Sanofi sued Lilly with respect to the '044 DCA injector pen patent even though, after reviewing the materials Lilly provided, its lawyers had no basis to conclude that Lilly's KwikPen was covered by any claim of the '044 patent.

215. At the time that Sanofi brought suit against Lilly, it acknowledged its market power over Lantus and its generic and follow-on versions. It pleaded that there were "[c]urrently . . . no generic or follow-on versions of Lantus® or of Lantus® SoloSTAR® approved by the [FDA] for sale in the United States."

216. Sanofi claimed that a launch of Lilly's Basaglar would cause Sanofi "irreparable harm for which they have no adequate remedy at law." Sanofi sought to have Lilly enjoined "from engaging in any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the insulin glargine [rDNA origin] injection in a prefilled insulin delivery device, 100 units/mL as claimed by the Patents-in-Suit for the full terms thereof (and any additional period of exclusivity to which Plaintiffs and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities."

217. Sanofi immediately capitalized its frivolous lawsuit – its stock soared. News of the lawsuit received great attention in the market. One analyst reported that the 30-month delay in Basaglar availability "would raise Sanofi's earnings per share from 2015 through 2020 by about 6 percent and reduce Lilly's EPS for the period by about 2 percent."[14]

218. On February 19, 2014, Lilly answered the complaint. It denied the charges of infringement. It asserted affirmative defenses of patent misuse and prosecution laches. It counterclaimed, seeking declarations of non-infringement, invalidity, and non-enforceability of the patents for patent misuse and prosecution laches. And it alleged the '864 and '044 patents

[14] Analysts observed that another purpose in Sanofi's delaying Lilly's approval was to allow Sanofi to attempt to transition the insulin glargine market to a different Sanofi insulin product, code-named U300. Sanofi had stated that U300 would not be submitted for FDA approval until at least the second quarter of 2014, which meant that Sanofi would not likely receive approval from the FDA until after February 2015, when Sanofi's '722 patent exclusivity for insulin glargine would expire. But if it could delay competition in the insulin glargine market beyond February 2015, it could obtain approval for its new U300 product and move purchases of insulin glargine to the new product before any competitor – including Lilly – could cut into its monopoly.

were improperly listed in the Orange Book; pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I), Lilly sought an order requiring Sanofi to delist the '864 and '044 patents from the Orange Book.

219. Lilly expressly pleaded the anticompetitive effect to Sanofi's lawsuit:

> Sanofi is aware that no claim of the patents-in-suit covers [Basaglar]. For example, before this action was filed, Lilly provided Sanofi with notice that the patents-in-suit do not cover [Basaglar], including reasons for why the claims of the patents-in-suit would not be infringed, and provided Sanofi's counsel with copies of documents identifying the formulation of [Basaglar] and a device by which it may be injected. Despite the information provided, Sanofi filed the present action with no reasonable bases for doing so. In maintaining this action, *Sanofi is attempting to extend the scope of the patents-in-suit with intended anticompetitive effects.* Accordingly, for at least these reasons, the patents-in-suit are unenforceable for patent misuse.

220. Lilly also alleged anticompetitive harm "[b]y reason of Sanofi's baseless litigation and/or attempt to expand the scope of the patents-in-suit, *with consequent harm to Lilly and other members of the public.*"

221. Lilly further alleged that "Sanofi's lawsuit triggered a 30-month stay that precludes Lilly from entering the market beyond February 2015 when the '722 patent exclusivity expires – a concrete harm to Lilly and the public that is the direct result of Sanofi's alleged anticompetitive conduct." Lilly further argued to the district court that anticompetitive harm existed due to "Lilly's intention to enter the market" and its "preparedness to do so, both of which are evidenced by Lilly's NDA, a significant filing demonstrating (1) actual and affirmative steps toward entering the market, and (2) Lilly's background, experience, and financial capability to enter."

222. On March 25, 2014, United States Patent No. 8,679,069 ("the '069 patent"), entitled "Pen-Type Injector," was issued by the PTO. It expires April 12, 2025. A true and correct copy of the '069 patent is attached as Exhibit M to this complaint. The '069 patent is

yet another in the string of DCA injector pen patents. After acquiring its rights to the patent, Sanofi listed the '069 patent in the Orange Book as claiming product 002, Lantus SoloSTAR. The listing of the '069 patent was unlawful for all the same reasons as the other DCA injector pen patents.

223. On May 14, 2014, Lilly sent a Sanofi a paragraph IV certification as to the '069 DCA injector pen patent, disclosing that Lilly had amended its paragraph IV certifications in its Basaglar NDA to include the '069 patent. In its letter, Lilly stated that its certification to the FDA alleges, *inter alia*, that the '069 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lilly's NDA product.

224. After receipt of Lilly's May certification, Sanofi amended its complaint in *Sanofi I* to assert infringement of the '069 patent. Lilly responded, repeating the similar denials, defenses and counterclaims as it had previously asserted (but now also applicable to the '069 patent).

P. Sanofi lacked any realistic likelihood of prevailing on the merits of *Sanofi I*.

225. A reasonable pharmaceutical company in Sanofi's position would not have reasonably expected to prevail in showing that Lilly's Basaglar infringed the '652 vial formulation patent.

226. The '652 vial formulation patent claimed the addition of polysorbate 20, polysorbate 80, or a poloxamer to an insulin glargine solution. If an insulin glargine product did not contain one of these molecules, it did not infringe the '652 patent. A reasonable pharmaceutical company would know that. Sanofi knew that.

227. Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, or a poloxamer. A reasonable pharmaceutical company that had received the portions of Lilly's 505(b)(2) application it provided to Sanofi would know that. Sanofi knew that.

228. Because the '652 vial formulation patent covered only insulin glargine products containing polysorbate 20, polysorbate 80, or a poloxamer, and Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, or a poloxamer, no reasonable pharmaceutical company would have expected to prevail on the merits of a claim that Lilly's Basaglar infringed the '652 vial formulation patent.

229. The '930 vial formulation patent claimed the addition of polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol to an insulin glargine solution. If an insulin glargine product did not contain one of these molecules, it did not infringe the '930 patent. A reasonable pharmaceutical company would know that. Sanofi knew that.

230. Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol to an insulin glargine solution. A reasonable pharmaceutical company that had received the portions of Lilly's 505(b)(2) application it provided to Sanofi would know that. Sanofi knew that.

231. Because the '930 vial formulation patent covered only products containing polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol, and Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol, no reasonable pharmaceutical company would have expected to prevail on the merits of a claim that Lilly's Basaglar infringed the '930 vial formulation patent.

232. The DCA injector pen patents claimed only a specific type of injector pen – that used in Lantus SoloSTAR – or aspects or mechanisms of that pen. If a different pen were used – a pen that did not encompass the aspects or mechanisms covered by the DCA injector pen patents, that injector pen would not infringe the DCA injector pen patents. A reasonable pharmaceutical company would know this. Sanofi knew this.

233. Lilly's KwikPen, which it disclosed it would use in conjunction with Basaglar, was different from the pen described in the DCA injector pen patents. A reasonable pharmaceutical company would know this. Sanofi knew this.

234. Because the DCA injector pens covered only certain types of pens (or aspects or mechanisms of those pens), and Lilly's KwikPen did not fall within that category of pens (and contained none of the aspects or mechanisms of those pens), no reasonable pharmaceutical company would have expected to prevail on the merits of a claim that Lilly's Basaglar (with its KwikPen) infringed the DCA injector pen patents.

235. Furthermore, a reasonable pharmaceutical company would have known that the DCA injector pen patents did not cover a drug substance, drug product, or method of using a drug. Accordingly, a reasonable pharmaceutical company would have known that it was not entitled to a 30-month stay of FDA approval under the Hatch-Waxman Amendments, simply by filing a suit over the DCA injector pens.

236. The formulation of Lantus disclosed in the '722 patent would enter the public domain in February 2015. If Sanofi's asserted vial formulation patents were construed as covering the Lantus formulation disclosed in the '722 patent, then the '722 disclosure would render the vial formulation patents invalid.

Q. Lilly receives tentative FDA approval for its NDA product.

237. In August 2014, the FDA granted tentative approval for Basaglar. Time to tentative approval was quick, coming exactly ten months after the application had been filed.

238. Basaglar did not then receive final approval due to the *Sanofi I* Hatch-Waxman litigation against Lilly. Were it not for Sanofi's wrongful Orange Book listings or Sanofi's filing of the frivolous patent litigation, the FDA would have granted Lilly final approval for Basaglar as soon as the '722 patent's pediatric exclusivity expired in February 2015. And with

final FDA approval for Basaglar, Lilly would have launched Basaglar at prices discounted from those of the Lantus products upon, or reasonably soon after, final approval.

239. Instead, Lilly was required to press on defending Sanofi's objectively meritless lawsuit. The parties engaged in substantial discovery, including interrogatories and document requests; subpoenaed non-parties; fought multiple discovery disputes; tendered experts and submitted *Daubert* motions opposing those experts; and undertook the nuanced and complex process of claim construction. Claim construction focused on issues like, for example, what constituted a polysorbate, and what constituted an ester or ether of a polyhydric alcohol, but did not reach the fact that Lilly's Basaglar contained no polysorbate or ester or ether of polyhydric alcohol, regardless of definition.

240. The litigation stretched through the remainder of 2014 and all the way until September 2015. For Sanofi, every day beyond February 15, 2015 that the litigation proceeded was a win. It meant another day on which a competing insulin glargine product could be kept off the market.

241. But its delay tactics could only last so long. The *Sanofi I* court held a final pre-trial conference on September 18, 2015 and set trial for September 28, 2015. The meritless nature of Sanofi's claims would soon be laid bare.

R. The Sanofi-Lilly settlement.

242. On September 28, 2015, the morning trial was set to begin, Lilly announced it had entered into a settlement agreement to resolve the patent litigation with Sanofi regarding its insulin glargine product, Basaglar. As a part of the agreement, Lilly and its alliance partner, Boehringer Ingelheim, would have the ability to launch Basaglar in the U.S. on December 15, 2016. The report stated that "[u]nder the terms of the agreement, Sanofi has granted Lilly a royalty-bearing license so Lilly can manufacture and sell Basaglar in the KwikPen® device

globally" but "details regarding the settlement [would remain] confidential." The announcement acknowledged that the FDA had "tentatively approved Basaglar [back] in August 2014" and that with the final "resolution, Lilly plans to request final approval of Basaglar from the FDA."

243. On September 28, 2015, the *Sanofi I* court signed and entered a Consent Judgment. In it, Sanofi finally admitted that Lilly's Basaglar did not infringe the vial formulation patents or DCA injector pen patents. And, even though the consent judgment memorialized Lilly's agreement to stall its Basaglar launch until December 15, 2016, the judgement provided the FDA with authority to grant final approval to Lilly's Basaglar NDA.

244. On October 16, 2015 Lilly advised the FDA of the consent decree and noted to the FDA that the consent decree stated: "This Consent Judgment constitutes a 'consent decree' pursuant to 21 U.S.C. § 355(c)(3)(C)(i)(II), such that Final Approval of Eli Lilly's NDA No. 205- 692 under 21 U.S.C. § 355(b)(2) may be granted on the date that this Consent Judgment is entered by the Court."

S. Lilly gets final FDA approval, but must wait due to the Sanofi-Lilly agreement.

245. On December 16, 2015, the FDA granted final approval to Lilly's Basaglar. The approval blessed the product that Lilly had filed an NDA for in 2013, and advised Sanofi about in its 2013 and 2014 paragraph IV certifications (and that was shown in the 66 pages of confidential documents provided by Lilly to Sanofi in January 2014).

246. Basaglar is a clear, colorless, sterile solution for injection: 100 units per mL (U-100) in a 3 mL prefilled delivery device (BASAGLAR KwikPen).

247. In approving Basaglar, the FDA noted that, Lilly could not use the term "biosimilar" to compare Basaglar to Lantus, because Lantus had not been licensed under the PHS. Nevertheless, the FDA's approval under section 505(b)(2) meant that Basaglar was

sufficiently similar to Lantus that data demonstrating Lantus's safety and efficacy also demonstrated Basaglar's safety and efficacy. Both contained the same molecular active ingredient – insulin glargine. Both acted in the human body in the same way. Basaglar was biologically similar to Lantus, even if it could not be called a "biosimilar."

248. Ordinarily, a company may launch its drug as soon as it obtains final approval. But, despite receiving final FDA approval on December 16, 2015, Lilly was forced to wait exactly a full year – until December 15, *2016* – to launch Basaglar. By filing a frivolous lawsuit, seeking to enforce patents for which there was no reasonable, objective expectation of success, Sanofi was able to leverage a settlement delaying the launch of Basaglar.

249. And it gets worse. Were it not for Sanofi's wrongful conduct, Lilly could have launched Basaglar even sooner, in February 2015. But for Sanofi's wrongful listing of the vial formulation patents and DCA injector pen patents in the Orange Book as covering Sanofi's Lantus cartridge formulation and Lantus SoloSTAR, it never could have sued Lilly for patent infringement under the Hatch-Waxman Amendments in the first place. It would not have been able to obtain and automatic 30-month stay in FDA approval of Basaglar.

250. Instead, Sanofi would have had to proceed under ordinary patent infringement law, which does not automatically enjoin the sale of a competing product. Lilly could have entered the insulin glargine market on February 16, 2015, unless Sanofi obtained a preliminary injunction preventing entry. But to obtain a preliminary injunction, Sanofi would have had to demonstrate a likelihood of succession the merits of its claim. But, as explained above, there was no objectively reasonable expectation of success on the merits. So Sanofi could not have enjoined Basaglar's launch beyond February 15, 2015.

251. In all, Sanofi's unlawful Orange Book listing and sham patent infringement litigation stalled the availability of follow-on insulin glargine products for 20 months. For a

drug worth $7 billion a year, that translates into an additional $11.7 billion in monopoly profits Sanofi was able to reap as a result of its scheme. And all the while, purchasers were forced to pay Sanofi's supra-competitive prices.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTIFFS AND THE CLASS

252. Sanofi's impairment of competition was hugely lucrative to Sanofi. Sanofi continues to sell Lantus and Lantus SoloSTAR in the United States. Allergan sold approximately $7 billion in Lantus and Lantus SoloSTAR products in 2014. This is hundreds of millions more in sales than Sanofi could have achieved absent its unlawful scheme to impair would-be competition. The entry of Lilly's Basaglar would have driven prices down, and/or eaten away at Sanofi's market share.

253. Sanofi's overarching anticompetitive scheme impaired and delayed the sale of competing insulin glargine products in the United States, and unlawfully enabled Sanofi to sell Lantus and Lantus SoloSTAR products at artificially-inflated prices. But for Sanofi's unlawful conduct, Lilly and other competitors would have been able to compete, unimpeded, with Sanofi's Lantus and Lantus SoloSTAR products.

254. But for defendants' anticompetitive conduct, as alleged above, other manufacturers of insulin glargine products would have entered the marketplace and effectively competed with Sanofi on or about February 15, 2015, when the pediatric exclusivity associated with Sanofi's Lantus formulation patents expired.

255. As a result, were it not for the Sanofi's anticompetitive conduct, the plaintiffs and other members of the class would have: (1) purchased lower-priced insulin glargine products instead of the higher-priced Lantus and Lantus SoloSTAR products for some or all of their insulin glargine needs; (2) paid a lower price for their insulin glargine products, sooner; and/or (3) paid lower prices for some or all of their remaining purchases.

256. Had Sanofi not wrongfully listed patents that did not claim Lantus in the Orange Book, and then sued Lilly to block its efforts to obtain 505(b) approval for a competing insulin glargine product, the market would have embraced Basaglar – which is more cost-effective than Lantus with the same safety and efficacy profile.

257. Within months, Lilly would have captured almost all or substantially all sales at lower prices, delivering substantial savings to the plaintiffs and other purchasers. As a result of Sanofi's anticompetitive scheme, however, competition has been very significantly impaired.

258. In fact, current events suggest substantial conversion of the market to Lilly's product: once Basaglar enters the market, CVS/Caremark – one of the three largest PBMs in the country – will remove Lantus from its 2017 formulary, and replace it with Basaglar. Had Sanofi not implemented its wrongful anticompetitive scheme, Lantus would have lost its CVS/Caremark business in February 2015.

259. During the relevant period, the plaintiffs and other purchasers bought substantial amounts of Lantus. The plaintiffs' and the other purchasers' prices for these products were substantially greater than the prices that they would have paid absent the unlawful conduct alleged herein.

260. As a consequence, the plaintiffs and other direct purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VII. MARKET POWER AND MARKET DEFINITION

261. At all relevant times, Sanofi had monopoly power in the market for insulin glargine because it had the power to raise or maintain the price of Lantus and Lantus SoloSTAR at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

262. At all times relevant to this case, there were only two long-acting, analogue insulin products available in the U.S., insulin glargine and insulin detemir. The products are not equivalent to one another, nor are they interchangeable. As explained above, they are different molecules with different mechanisms of action.

263. A small but significant, non-transitory increase to the price of the Lantus and Lantus SoloSTAR would not have caused a significant loss of sales.

264. Lantus and Lantus SoloSTAR do not exhibit significant, positive cross-elasticity of demand with respect to price with any other insulin product other than other insulin glargine products.

265. Sanofi needed to control only Lantus and Lantus SoloSTAR and their generic or follow-on equivalents, and no other products, in order to maintain the price of the Lantus franchise profitably at supra-competitive prices. Only the market entry of competing, insulin glargine products would render Sanofi unable to profitably maintain their prices for Lantus and Lantus SoloSTAR without losing substantial sales.

266. The defendants also sold Lantus and Lantus SoloSTAR products at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

267. The defendants have had, and exercised, the power to exclude competition to Lantus and Lantus SoloSTAR.

268. The defendants, at all material times, enjoyed high barriers to entry with respect to the brand and generic Lantus and Lantus SoloSTAR.

269. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Sanofi's ability to control the prices of Lantus and Lantus SoloSTAR.

270. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Sanofi's ability to control the prices of the Lantus and Lantus SoloSTAR products, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, (a) the fact that competing insulin glargine products would have entered the market at substantial discounts to the brand versions, but for Sanofi's anticompetitive conduct; and (b) the gross margin was at all times substantial enough to show market power, with the price at least 60% higher than cost of production.

271. To the extent proof monopoly power by defining a relevant product market is required, the plaintiffs allege that the relevant antitrust market is the insulin glargine market.

272. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

273. Sanofi's market share in the relevant market was 100% at all relevant times and will remain so until the launch of Lilly's insulin glargine product in or about December 2016.

VIII. MARKET EFFECTS

274. Sanofi willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. Sanofi designed this scheme to delay competition on the merits, for the anticompetitive purpose of forestalling competition against its Lantus product franchise. Sanofi carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

275. Sanofi implemented the scheme as described herein. These acts, in combination and individually, were undertaken to serve Sanofi's anticompetitive goals.

276. Sanofi's acts and practices as described herein had the purpose and effect of restraining competition unreasonably and injuring competition by protecting its Lantus

products from competition. These actions allowed Sanofi to maintain a monopoly and exclude competition in the market for Lantus, Lantus SoloSTAR, and other insulin glargine products, to the detriment of the plaintiffs and all other members of the direct purchaser class.

277. Sanofi's exclusionary conduct has delayed competition and unlawfully enabled it to sell Lantus and Lantus SoloSTAR products without competition. Were it not for the illegal conduct, one or more competitive insulin glargine products would have entered the market sooner.

278. By way of example, and not limitation, in the absence of Sanofi's conduct: (i) a more affordable version of insulin glargine would have become available beginning in or around February 2015, and; (ii) direct purchasers, such as the plaintiffs and other members of the class, would have purchased less supra- competitively-priced Lantus and Lantus SoloSTAR and instead purchased Lilly's less expensive competitor product.

279. Sanofi's illegal acts and conspiracy to foreclose introduction into the U.S. marketplace of any competing insulin glargine product caused the plaintiffs and all members of the class to pay more than they would have paid for the Lantus products absent this illegal conduct.

280. When a competitor drug enters a previously-monopolized market, the price to purchasers drops. As a result, direct purchasers substitute less expensive versions of the drug for some or all of their brand purchases. This price competition enables all direct purchasers of the drugs to purchase competitive products at a lower price, and/or purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition.

281. Thus, Sanofi's unlawful conduct deprived the plaintiffs and members of the class of the benefits from competition that the antitrust laws are designed to ensure.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

282. During the relevant time period, the defendants sold and will sell Lantus and Lantus SoloSTAR across state lines.

283. During the relevant time period, the plaintiffs and members of the class purchased substantial amounts of Lantus and Lantus SoloSTAR directly from the defendants, and will begin to purchase substantial amounts of insulin glargine from Lilly. As a result of Sanofi's illegal conduct, as described herein, the plaintiffs and the members of the class were compelled to pay, and did pay, artificially inflated prices for their insulin glargine products, Lantus and Lantus SoloSTAR.

284. During the relevant time period, Sanofi used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

X. CLASS ACTION ALLEGATIONS

285. The plaintiff brings this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3).

> All persons or entities in the United States and its territories, or subsets thereof, that purchased Lantus cartridges or Lantus SoloSTAR directly from Sanofi at any time between February 13, 2015 and December 31, 2016 or until the anticompetitive effects of Sanofi's conduct cease (the "class").

286. Excluded from the class are Sanofi U.S., Sanofi GmbH, and any officers, directors, management, employees, subsidiaries, and affiliates.

287. Members of the direct purchaser class are so numerous and geographically dispersed that joinder of all members is impracticable. The plaintiffs believe that the class is

numerous and widely dispersed throughout the United States. The class is readily identifiable from information and records in Sanofi's possession.

288. The plaintiff's claims are typical of the claims of the members of the class. The plaintiffs and all members of the direct purchaser class were damaged by the same wrongful conduct of the defendants – i.e., as a result of the defendants' conduct they paid artificially inflated prices for the Lantus products.

289. The plaintiff will fairly and adequately protect and represent the interests of the class. The interests of the plaintiffs are coincident with, and not antagonistic to, those of the other members of the class.

290. Counsel that represent the plaintiffs are experienced in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

291. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

292. Questions of law and fact common to the class include:

i. Whether the defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

ii. Whether the polysorbate formulation patents claimed Lantus cartridges or Lantus SoloSTAR;

iii. Whether Lantus cartridges contained polysorbate 20 or polysorbate 80;

iv. Whether Lantus SoloSTAR contained polysorbate 20 or polysorbate 80;

v. Whether the polysorbate formulation patents could be asserted against a would-be Lantus competitor, like Lilly;

vi. Whether Sanofi had any reasonable basis to argue that the polysorbate formulation patents should be enforced against a would-be Lantus cartridge or Lantus SoloSTAR competitor;

vii. Whether Sanofi's assertion of the polysorbate formulation patents against Lilly did in fact frustrate competition;

viii. Whether Lilly's injector pen infringed the DCA injector pen patents;

ix. Whether Sanofi had any objectively reasonable basis to argue that the DCA injector pen patents should be enforced against Lilly;

x. Whether Sanofi's assertion of the DCA injector pen patents against Lilly was intended to frustrate competition;

xi. Whether Sanofi's assertion of the DCA injector patents against Lilly did, in fact, frustrate competition;

xii. Whether there exist any legitimate procompetitive reasons for some or all of Sanofi's conduct;

xiii. To the extent such justifications exist, whether there were less restrictive means of achieving them;

xiv. Whether direct proof of Sanofi's monopoly power is available and, if so, whether it is sufficient to prove Sanofi's monopoly power without the need to define the relevant market;

xv. Whether Sanofi's scheme, in whole or in part, has substantially affected interstate commerce;

xvi. Whether Sanofi's scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiffs and the members of the class;

xvii. Whether all of the defendants conspired to suppress competition for Lantus cartridges or Lantus SoloSTAR;

xviii. Whether, in the absence of Sanofi's anticompetitive conduct, Lilly's competing insulin glargine product would have entered the market on or around February 15, 2015;

xix. Whether, as a result of Sanofi's anticompetitive conduct, direct purchasers were overcharged for their insulin glargine purchases;

xx. Whether Sanofi's anticompetitive conduct was a substantial

contributing factor in causing delayed availability of competing insulin glargine products;

xxi. A reasonable estimate the delay occasioned by Sanofi's wrongful conduct; and

xxii. The quantum of overcharges paid by the class in the aggregate.

293. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

294. The plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT ONE – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)

(Overall Monopolization Scheme)

295. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

296. At all relevant times, Sanofi possessed monopoly power in the relevant market and possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

297. The defendants engaged in an exclusionary conduct scheme that included at various times each of the following acts (among others):

i. Improperly listing the '652 patent in the Orange Book as covering Lantus cartridges and Lantus SoloSTAR;

ii. Improperly listing the '930 patent in the Orange Book as covering Lantus cartridges and Lantus SoloSTAR;

iii. Improperly listing the '833 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug;

iv. Improperly listing the '297 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug;

v. Improperly listing the '864 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug;

vi. Improperly listing the '044 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug; and

vii. Commencing and maintaining a sham litigation against Lilly to delay introduction of competing insulin glargine products into the U.S. market

298. The goal, purpose, and/or effect of Sanofi's scheme was to maintain and extend its monopoly power with respect to insulin glargine products – sold under the brand names Lantus and Lantus SoloSTAR. Sanofi's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any competing versions of the insulin glargine products enabled Sanofi to continue charging supra-competitive prices for the products without a substantial loss of sales.

299. If manufacturers of competing insulin glargine products had not been prevented by Sanofi from entering the market, the plaintiffs and members of the class would have purchased lower-priced insulin glargine products for some or all of their insulin glargine product requirements, and/or would have received lower prices on some or all of their remaining Lantus or Lantus SoloSTAR purchases, at earlier periods of time and in far greater quantities.

300. As a result of Sanofi's illegal scheme, the plaintiffs and the class paid more than they would have paid for insulin glargine products, absent the illegal conduct. But for the illegal conduct, competitors would have begun marketing competing versions of insulin glargine, resulting in cost savings to the plaintiffs and direct purchasers.

301. During the relevant period, the plaintiffs and the class purchased substantial amounts of Lantus and Lantus SoloSTAR directly from Sanofi. As a result of Sanofi's illegal conduct, the plaintiffs and the members of the class were compelled to pay, and did pay, artificially-inflated prices for their insulin glargine product requirements. The plaintiffs and all class members paid prices for Lantus and Lantus SoloSTAR that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced drugs instead of expensive Lantus and Lantus SoloSTAR; and/or (b) the price of Lantus and Lantus SoloSTAR was artificially inflated by Sanofi's illegal conduct.

302. The anticompetitive consequences of Sanofi's actions far outweigh any arguable procompetitive benefits. Sanofi acquired and extended a monopoly through unlawful means.

303. Sanofi's scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for insulin glargine products in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT TWO – ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT
(15 U.S.C. § 2)

(Attempted Overall Monopolization Scheme)

304. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

305. At all relevant times, Sanofi possessed substantial power (i.e., monopoly power) or possessed a dangerous probability of achieving monopoly power.

306. With the specific intent to achieve a monopoly, Sanofi attempted to acquire and/or willfully maintain monopoly power by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for insulin glargine products.

307. The goal, purpose, and effect of Sanofi's conduct was to delay and impair the sale of competing insulin glargine products in the United States at prices below Sanofi's prices for Lantus and Lantus SoloSTAR, thereby effectively preventing the average market price for Lantus, Lantus SoloSTAR, and their follow-on products from declining dramatically.

308. By engaging in the foregoing conduct, Sanofi has intentionally and wrongfully attempted to monopolize the relevant market in violation of the Sherman Act.

309. But for Sanofi's unlawful conduct, other manufacturers would have launched competing insulin glargine products.

310. The plaintiff and members of the class have been injured in their business or property by reason of Sanofi's antitrust violations alleged herein. Their injuries consist of: (a) being denied the opportunity to purchase lower-priced insulin-glargine products; and (b) paying higher, supra-competitive prices for Lantus and Lantus SoloSTAR than they would have paid in the absence of Sanofi's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Sanofi's conduct unlawful.

XII. DEMAND FOR JUDGMENT

311. WHEREFORE, the plaintiff, on behalf of itself and the proposed class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that

reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the class, and declare the plaintiffs as the representative of the class;

b. Enter joint and several judgments against the defendants and in favor of the plaintiffs and the class;

c. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

d. Award the plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

312. Pursuant to Fed. Civ. P. 38, the plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: December 30, 2017

Respectfully submitted,

/s/ Thomas M. Sobol
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